510(k) SUMMARY

MAY 2 1 2013

DATE: November 13, 2012

SUBMITTER:
Sorin Group USA, Inc.
14401 West 65th Way
Arvada, Colorado 80004-3599
Device Establishment Registration Number: 1718850

CONTACT PERSON:
Scott Light
Phone: (303) 467-6313
Fax: (303) 467-6502
E-mail: scott.light@sorin.com

DEVICE CLASSIFICATION:

Suture component:
Class II per 21 CFR §878.5000,
Product Code: GAT

Cannula component:
Class II, per 21 CFR §876.1500,
Product Code: GCJ

PREDICATE DEVICES: Pre-tied loop suture cannula, Ethicon Inc., K925914, Class II, GCJ, 21 CFR §876.1500

CONTRACT MANUFACTURER:
B. Braun Medical Inc.
Allentown, PA 18109-9341
(610) 266-0500
Device Establishment Registration Number: 2523676

DEVICE DESCRIPTION:

The VascuLoop Two Tie Endoscopic Ligation System is used during endoscopic vessel harvesting to ligate both ends of the vessel being harvested at the sites where it is to be cut. The cannula allows the ligation loops to be placed and tightened from a single central incision.

The product consists of a nylon cannula, tapered at both ends, with a braided polyester suture (B. Braun/Aesculap PremiCron®, 510(k) cleared by K012201) that has a closable loop tied in one end with the free end threaded through the cannula.

This assembly is packaged in a paper envelope and sealed in a Tyvek – poly coextrusion pouch with appropriate labeling. The product will be sterilized using Ethylene Oxide gas.

The Sorin VascuLoop product will be assembled, packaged, and sterilized by B. Braun Medical Inc. The instructions for use for both the VascuLoop and the PremiCron® suture are included in the packaged product.

INTENDED USE:

The VascuLoop is used for proximal and distal ligation of vessels during endoscopic vessel harvesting procedures.

SUBSTANTIAL EQUIVALENCE:

Ethicon Inc.'s Pre-tied loop suture cannula, FDA cleared by K925914, is the predicate device used for substantial equivalence comparison. The Ethicon product brand chosen for this comparison was the Ethicon EndoLoop™ with Ethibond™ Excel suture. The Sorin VascuLoop has the same intended use as Ethicon's EndoLoop™.

Both the Sorin and Ethicon devices provide:

- A size 0 polyester suture with a pre-tied Duncan loop to perform the intended vessel ligation action
- A nylon cannula with tapered ends to use for loop placement and closure
- The same recommendations for the user-tied loop for in-situ vessel ligation.

The only differences between the proposed and predicate devices include a different suture used (PremiCron®), a different packaging configuration for the finished device, and a different manufacturer assembling, packaging, and sterilizing the device.

CONCLUSION:

Functional performance testing conducted with the proposed device, simulated use cadaver study, and the similarities between the Sorin VascuLoop and Ethicon Inc.'s Pre-tied suture cannula (EndoLoop™) in design, materials, and intended use demonstrate that the VascuLoop with PremiCron® Braided Polyester Suture is as safe and effective as the predicate device and can be considered substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

May 21, 2013

Sorin Group USA, Inc.
% Mr. Scott Light
Regulatory Affairs Manager
14401 West 65th Way
Arvada, Colorado 80004-3599

Re: K122735
Trade/Device Name: VascuLoop Two Tie Endoscopic Ligation System
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT, GCJ
Dated: May 15, 2013
Received: May 16, 2013

Dear Mr. Light:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, For

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122735

Device Name: VascuLoop Two Tie Endoscopic Ligation System made with PremiCron® Braided Polyester Suture

Indications For Use:

The Sorin VascuLoop is used for proximal and distal ligation of vessels during endoscopic vessel harvesting procedures.

Prescription Use ___X___ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE, IF NEEDED)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K122735